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1907-1993

October 6, 1999

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 106 1
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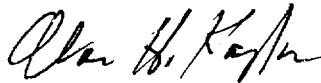
Re: Docket No. 99P-1589: Reply of Purdue Pharma L.P. to
Counsel for Roxane Laboratories' Letter of October 4,
1999 to Kim E. Dettelbach, Esq.

Dear Sir/Madam:

In the above-referenced letter (copy attached as Exhibit 8), counsel for Roxane Laboratories, Inc., gave notice that, effective November 18, 1999, Roxane will no longer be committed to withhold from the market RoxicodoneTM SR, the product which is the subject of the Petitions filed by Purdue Pharma L.P. in this Docket. Counsel's letter also stated that "[w]e look forward to an expeditious resolution of the issues raised in the Purdue petitions." In light of counsel's letter, there is now an imminent need for FDA to rule on Purdue's Petitions.

In order to provide ample time for an appropriate Court to consider the matter in the event FDA does not grant the requested relief, Purdue requests that FDA rule on the merits of its Citizen Petition by October 29, 1999. In the alternative, Purdue requests that FDA rule by that date on Purdue's Petition for Stay of Action. If there is any question about the agency's ability to make a determination on either Petition by the requested date, please let us know as soon as possible so that potential alternate means of assuring an orderly review can be considered.

Respectfully submitted,



Alan H. Kaplan
Richard S. Morey
Peter R. Mathers

Counsel for Purdue Pharma L.P.

99P-1589

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KLEINFELD, KAPLAN AND BECKER

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cc: Kim E. Dettelbach, Esq.
 Elizabeth Dickinson, Esq.
 Donald Beers, Esq.
 James Morrison

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October 4, 1999

VIA HAND DELIVERY

Kim E. Dettelbach, Esq.
Office of the Chief Counsel (GCF-1)
Food and Drug Administration
Room 6B20
5600 Fishers Lane
Rockville, MD 20857

Re: Citizen Petition and Petition for Stay filed by Purdue Pharma L.P., Docket
No. 99P-1589

Dear Kim:

As you know, we represent Boehringer Ingelheim Corporation and its subsidiary, Roxane Laboratories, Inc. (collectively "Roxane"), with respect to the above-referenced petitions. By letter dated June 9, 1999 addressed to Elizabeth Dickinson of your office, I confirmed an oral commitment I made, on behalf of Roxane, to provide the Food and Drug Administration 45 days notice prior to Roxane's commencement of sale of the extended release oxycodone product that is the subject of the Purdue petitions. This letter constitutes that notice.

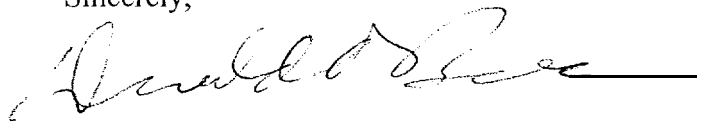
Roxane has not established an exact launch date with respect to this product and it may not begin shipment on November 18, 1999, the date 45 days from today. It will not, however, begin shipments to customers before that date.

As you know, Roxane feels strongly that the FDA's approval of its new drug application for this product was and continues to be appropriate. We look forward to an expeditious resolution of the issues raised in the Purdue petitions.

Kim E. Dettelbach, Esq.
October 4, 1999
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If you have any questions about our position in this matter, please feel free to
contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Donald O. Beers", followed by a horizontal line.

Donald O. Beers

cc: Alan H. Kaplan, Esq.